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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,320	08/17/2005	Nathan Charles Brown	J3672(C)	6742

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EXAMINER	
BROWN, COURTNEY A	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
09/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/518,320	BROWN ET AL.	
	Examiner	Art Unit	
	COURTNEY BROWN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/01/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 1, 2009 has been entered.

Acknowledgement of Receipt/Status of Claims

This Office Action is in response to the amendment filed June 1, 2009. Claims 1-7 and 9-13 are pending in the application. Claim 8 has been cancelled. Claims 1, 3, 9 and 10 have been amended. Claim 13 is newly added. Claims 1-7 and 9-13 are being examined for patentability.

Information Disclosure Statement

The information disclosure statement filed October 7,2008 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but all of the information

referred to therein has not been considered. The Examiner notes that this was previously noted in the Final Office Action filed March 2, 2009.

Applicant's arguments, see pages 13-20, filed June 1, 2009, with respect to the rejection(s) of claim(s) 1-7 and 9-12 under 35 USC 103 (a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection has been made below.

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Withdrawn Rejections

The rejection of claim 1 under 35 U.S.C. 112, second paragraph has been **withdrawn.**

The rejection of claims 1-12 under 35 U.S.C. 103(a) as being unpatentable over Cai et al. (US Patent 6,451,295 B1) in view of Rieley et al. (US 2002/0119108 A1) has been **withdrawn.**

Response to Arguments

Applicant's arguments, filed June 1, 2009, with respect to the 35 U.S.C. 112, second paragraph rejection of claim 1 have been considered but are moot in view of Applicant's amendment.

Applicant's arguments, filed June 1, 2009, with respect to the 103 rejection of claims 1-12 are rejected under 35 U.S.C. 103(a) over Cai et al. (US Patent 6,451,295 B1) in view of Rieley et al. (US 2002/0119108 A1) have been considered but are moot in view of the new ground(s) of rejection.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a water and oil emulsion composition comprising an oil continuous phase and at least one aqueous dispersed phase wherein the proportion of aqueous dispersed phase (s) within the total composition is from 50-90% by weight, excluding any volatile propellant that may be present. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that the compositions of the invention comprise at least one aqueous dispersed phase wherein the proportion of aqueous dispersed phase(s) within the total composition (excluding any volatile propellant that may be present) is typically from 50% to 90%, particularly from 50% to 70% when used in stick compositions and particularly from 70% to 90%, especially from 75% to 85%, when used in liquid or cream/soft solid compositions (see page 5, lines 7-12 of instant specification).

2) Nature of the invention

The nature of the invention is directed to a w/o emulsion antiperspirant composition comprising an oil continuous phase and at least one aqueous dispersed phase wherein the composition further comprises a dissolved antiperspirant salt, an emulsifier and a polymer comprising Brønsted acid groups.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of cosmetic research has the capability of understanding the scientific and engineering principles applicable to the cosmetic industry and possesses a degree in a scientific discipline such as organic synthetic chemistry, polymer chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

The art teaches that an emulsion type depends on the emulsifiers and relative amounts of the two liquid phases (see *Remington's Pharmaceutical Sciences 17th Edition*, 1985 bottom right of page 317). Thus more water provides and oil in water emulsion and more oil provides a water in oil emulsion. For example, Remington's teaches an example of oil in water emulsion (page 325, column 1) wherein said emulsion has twice as much water than oil (i.e., 100 g of water versus 50 g of oil).

5) Level or degree of predictability, or a lack thereof, in the art

A water in oil emulsion means that water is dispersed in the oil. Hence, there would be more oil than water because the oil is the continuous phase. However, if there is 70-90% by weight water and only 30-10% oil, an oil in water emulsion is produced (see the diagram below). Remington's teaches that wherever possible, the volume of

the dispersed phase should not exceed 50% of the total volume of the emulsion (page 327, bottom right). Thus, the dispersed phase should be less than 50% otherwise inversion will result. Thus, there is a lack of predictability in the art of formulating a water in oil emulsion composition comprising an oil continuous phase and at least one aqueous dispersed phase wherein the proportion of aqueous dispersed phase (s) within the total composition is from 70-90% or even 50-90% by weight, excluding any volatile propellant that may be present.

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how to make and use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. The instant specification discloses examples (see pages 20-25) using an aqueous dispersed phase comprising Aloxicoll ® L which is a 50% aqueous solution of aluminum chlorohydrate. BK Giulini, the manufacturer of Aloxicoll ® L, teaches that Aloxicoll ® L forms clear solutions in formulations with alcohol concentration up to 50% volume and that above this concentration, small quantities of said aluminum chlorohydrate may precipitate out. Further, BK Giulini teaches that Aloxicoll ® powders are stable under non aqueous conditions (see page 1 of *Aloxicoll ®L Standard Antiperspirant Active*, Form AP-L-e-10/06).

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to a water and oil emulsion composition comprising an oil continuous phase and

at least one aqueous dispersed phase wherein the proportion of aqueous dispersed phase(s) within the total composition is from 50-90% by weight, excluding any volatile propellant that may be present.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct a myriad number of experiments comprising water and oil emulsion compositions where the conventional wisdom is that, for example, an emulsion with 90% aqueous and 10% oil would be oil in water emulsion and not water in oil emulsion as instantly claimed. Essentially, one of ordinary skill in the art is left in the dark and has to figure out how to do this themselves. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to try to figure out how to make water in oil emulsion with 90% aqueous phase and 10% oil phase which goes against the conventional knowledge in the art.

Therefore, in view of the Wands factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to conduct an undue amount of experimentation to determine if this invention actually works.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joshi et al. (US Patent 6,171,581 B1) in view of Galleguillos et al. (US Patent 5,534,245) and Rieley et al. (US 2002/0119108 A1).

Applicant's Invention

Applicant claims a w/o emulsion antiperspirant composition comprising an oil continuous phase and at least one aqueous dispersed phase, wherein the composition further comprises a dissolved antiperspirant salt, an emulsifier and, in a disperse phase separate from the dissolved antiperspirant salt, a polymer comprising Brønsted acid groups wherein the dissolved antiperspirant salt is in an aqueous dispersed phase and the polymer comprising Brønsted acid groups is in a phase separate from that of the dissolved antiperspirant salt, and wherein the proportion of aqueous dispersed phase (s) within the total composition is from 50% to 90% by weight, excluding any volatile propellant that may be present. Applicant is enabled for a w/o emulsion antiperspirant composition comprising 50% by weight of an aqueous dispersed phase.

Determination of the scope and the content of the prior art (MPEP 2141.01)

Joshi et al. teach water and oil emulsion solid antiperspirant or deodorant compositions comprising by weight of the total composition: **0.1-30%** of a **silicone elastomer** (emulsifier component of instant invention)**;** 0.05-30% of a gellant,; 1-25% of

an **antiperspirant** or deodorant active;**1-90% wate**r and 1-75% **oil** (abstract) wherein said emulsion composition is solid at room temperature and may be a water-in-oil or an **oil-in-water** emulsion (column 1, lines 55-60). The oils used may be volatile or nonvolatile wherein silicone elastomers are often purchased in the form of gels of the elastomer in a **volatile or nonvolatile silicone**. The oil present in said emulsion composition may be found as part of the elastomer composition alone, the oil phase alone, or **both** (column 11, lines 40-55). Suitable gellants are carboxylated salt gelling agents (Brønsted acid group of instant application) wherein the term "carboxylated salt gelling agent" means a gelling agent that is formed by the reaction of a salt with a compound containing at least one carboxylic acid group (column 4, lines 15-57). Joshi et al. teach that other suitable gelling agents are various fatty acids having the general formula **R--COOH** wherein R is a straight or branched chain alkyl which may be unsubstituted, or substituted with one or more hydroxyl groups (column 10, lines 10-24). Preferably, the antiperspirant salts are completely dissolved in the water phase and in some cases small amounts of salts may not be dissolved, i.e. may remain in the crystalline or suspensoid form (column 11, lines 5-10).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the invention of the instant application and that of Joshi et al. is that Joshi et al. do not expressly teach the use of a polymer comprising Brønsted acid groups. This deficiency in Joshi et al. is cured by the teaching of Galleguillos et al. Galleguillos et al. teach antiperspirant deodorant compositions comprising a hydrophilic polymer selected from the group consisting of an ethoxylated, propoxylated or carboxylated hydrophilic polyurethane wherein the polyurethane backbone can be substituted with hydroxyl or carboxyl groups to improve the water solubility or dispersibility of the hydrophilic polymeric binder (column 7, line 6 bridging to column 8, lines 1-11).

The difference between the invention of the instant application and that of Joshi et al. is that Joshi et al. do not expressly teach the use of polymer comprising Brønsted acid groups wherein said polymer is either suspended as a solid in the oil continuous phase (instant claim 2) or emulsified as a separate aqueous dispersed phase (instant claim 3). This deficiency in Joshi et al. is cured by the teaching of Rieley et al. Rieley et al. teach antiperspirant products utilizing compositions comprising an antiperspirant salt and a water soluble polymer, characterized in that: (i) the polymer comprises Brønsted acid groups and acts as a co-gellant for the antiperspirant salt when mixed therewith in the presence of water; and (ii) the polymer is physically separate from antiperspirant salt prior to application (abstract).

The difference between the invention of the instant application and that of Joshi et al. is that Joshi et al. do not expressly teach level less than 4 mmole/g (instant claim 7) of Brønsted acid groups in the polymers as well as said Brønsted acid groups having

an acid value greater than 320(instant claim 12). This deficiency in Joshi et al. is cured by the teaching of Rieley et al. Rieley et al. teach antiperspirant products comprising Bronsted acid groups that are preferably present at a concentration of greater than 0.1 mmole per gram of polymer, more preferably at a concentration of greater than 1.0 mmole per gram of polymer, and most preferably at a concentration of greater than 3.0 mmole per gram of polymer ([0023]). Reiley et al. also teach that the acid value of a polymer is a widely used means of characterization. Acid values generally express the acidity of a polymer in terms of the number of milligrams of potassium hydroxide base required to fully neutralize one gram of the polymer. Preferred polymers have acid values greater than 320 or even greater than 450 ([0025-0026]).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the cited references to arrive at a w/o emulsion antiperspirant composition comprising a polymer comprising Brønsted acid groups.

Galleguillos et al. teach that the optically-clear gelled emulsions often exhibit the disadvantages of composition instability during storage; the development of a hazy or milky appearance during storage; a stringy, tacky, oily consistency and other undesirable esthetics(column 2, line 59 bridging to column 3, lines 1-20). Galleguillos et al. teach that transparency had been difficult to achieve in roll-on or gel antiperspirant compositions because the gelling agents either interacted with the antiperspirant compound or were ineffective at a low pH of about 2 to about 6 (column 11, lines 42-

46). In addition, Galleguillos et al. teach that emulsion gel compositions often leave a visible residue in the form of a white layer on the skin or clothing (column 2, line 59 bridging to column 3, lines 1-20). On the contrary, hydrophilic polymers tolerate a pH of about 2 to about 6, and resist precipitation from solution in the presence of a relatively high salt concentration, act as a viscosity modifier or thickener, and do not contribute to whitening of skin or clothing (column 6, lines 58-67 of Galleguillos et al.). One skilled in the art would have been motivated to formulate a w/o emulsion antiperspirant composition comprising a polymer comprising Brønsted acid groups with the expectation of an optically clear antiperspirant composition that does not form a visible residue on the skin or clothing. Therefore, given the state of the art as evidenced by the teachings of the cited references, and absent any evidence to the contrary, there would have been a reasonable expectation of success in combining the teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the cited references to arrive at a w/o emulsion antiperspirant composition comprising a polymer comprising Brønsted acid groups wherein said polymer is either suspended as a solid in the oil continuous phase or emulsified as a separate aqueous dispersed phase.

Rieley et al. teach that it is desirable that the interaction between the antiperspirant salt and the polymer does not occur significantly before they are brought into contact with the human body. Such premature interaction can result in numerous problems including unwanted thickening of the product, poor

dispensing, poor sensory properties, and poor antiperspirancy and/or deodorancy performance. Rieley et al. teach that avoidance of premature interaction involves keeping the polymer physically separate from the AP salt which may be achieved with a composition comprising a non-interacting mixture of the AP salt and the polymer ([0016-0017]). One skilled in the art would have been motivated to formulate a w/o emulsion antiperspirant composition comprising a polymer comprising Brønsted acid groups wherein said polymer is either suspended as a solid in the oil continuous phase or emulsified as a separate aqueous dispersed phase with the expected benefit of minimizing or eliminating the interaction between the antiperspirant salt and the polymer before they are brought into contact with the human body. Therefore, given the state of the art as evidenced by the teachings of the cited references, and absent any evidence to the contrary, there would have been a reasonable expectation of success in combining the teachings of the cited references.

With regard to claims 7 and 12, Riely et al. do provide data for these limitations. In addition, Reiley et al. teach that **acid values may be measured experimentally or may be estimated theoretically ([0026]).** The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Claim 10 is a product-by-process claim. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Accordingly, in view of the cited references and that knowledge generally available to the ordinarily skilled artisan, it is apparent that such individual would have been motivated to combine the teachings of the respective references in the manner of Applicant to arrive at the claimed invention.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited references.

Conclusion

The claims remain rejected.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electron Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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